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No. 97-_____

# In the Supreme Court

OF THE

# United States

OCTOBER TERM, 1997

BECTON DICKINSON VASCULAR ACCESS, INC.,
*Petitioner,*

v.

CRITIKON, INC.,
*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## PETITION FOR WRIT OF CERTIORARI

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December 23, 1997

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## QUESTIONS PRESENTED

1. May a patentee, whose patent specification does not enable one of ordinary skill in the art to make and use the claimed invention, as required by 35 U.S.C. § 112, supplement that specification by referring to prior art published *after* the patentee's application was filed?

2. Did the Court of Appeals for the Federal Circuit fail to give due regard to the opportunity of the trial court to judge the credibility of the witnesses, as required by Rule 52 (a), F.R.Civ.P, in making its own finding of fact concerning the independent development of petitioner's accused product?

3. Did the Court of Appeals for the Federal Circuit misapply the standard for determining whether an opinion of counsel concerning patent invalidity or non-infringement is sufficiently competent to be reasonably relied upon by a party in making a decision whether to manufacture and market a product that could be charged with infringement?

## RULE 29.1 STATEMENT

Petitioner Becton Dickinson Vascular Access, Inc. was the defendant-appellant below and is the wholly owned subsidiary of Becton Dickinson and Company.

Respondent Critikon, Inc, was the plaintiff-appellee below. Critikon, Inc, has affiliates, Johnson & Johnson Inc. and Johnson & Johnson Medical Inc. Johnson & Johnson Inc. is the parent company to Johnson & Johnson Medical Inc. Johnson & Johnson Medical Inc. is the successor in interest of Critikon Inc.

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BECTON DICKINSON VASCULAR ACCESS, INC.,
*Petitioner,*

v.

CRITIKON, INC.,
*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## PETITION FOR WRIT OF CERTIORARI

Becton Dickinson Vascular Access, Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

## OPINIONS BELOW

The August 12, 1997 opinion of the Federal Circuit is reported at 120 F.3d 1253 (Fed. Cir. 1997), and is reproduced beginning at Appendix page 2a. The July 18, 1994 memorandum opinion of the District Court is reproduced beginning at Appendix page 19a.

## JURISDICTION

The Federal Circuit denied petition for rehearing and declined suggestion for rehearing *en banc* on September 24, 1997. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 112 provides in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. § 131 provides:

> The Commissioner shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor.

35 U.S.C. § 132 provides in pertinent part:

> . . . No amendment shall introduce new matter into the disclosure of the invention.

Rule 52(a) of Title 28, F.R.Civ.P, provides in pertinent part:

> . . . Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. . . .

## STATEMENT OF THE CASE

This is a patent infringement action involving intravenous catheter devices. Respondent charged that petitioner's "safety catheter" device infringed U.S. Patent No. 4,952,207 (the "Lemieux" patent)[1] and that the use of petitioner's device infringed U.S. Patent No. 4,978,344, (the "Dombrowski" patent).

### A. Background

Intravenous catheters consist of thin plastic tubes that are inserted into veins so that fluids can be introduced into the body. To permit insertion into a vein, catheters are mounted over introducer needles. After the catheter-needle assembly is inserted, the needle is withdrawn, leaving the catheter within the vein. Safety catheters have a "needle guard" that is positioned over the tip of the needle as the needle is withdrawn from the catheter to protect health care workers from accidental needle sticks.

### B. The Patents-In-Suit

#### 1. *The Dombrowski Patent*

The Dombrowski patent discloses a "needle and catheter assembly." Dombrowski teaches that a "tether" is essential to the operation of his invention. The tether prevents the needle guard from falling off after the needle is withdrawn from the catheter. Undisputed testimony below established that, without the tether, the Dombrowski "device would be nonfunctional according to its intended purpose" and the

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[1]Respondent requested that the United States Patent and Trademark Office reissue the Lemieux patent under 35 U.S.C. § 251 on December 5, 1991. During the course of the litigation, the Lemieux patent reissued as U.S. Patent No. RE34,416. Respondent amended its complaint to add claims of infringement as to that patent.

"only way that Dombrowski teaches his patent to be done is to have a tether."

Nevertheless, claims 18 and 19 of Dombrowski's patent (the only claims of that patent asserted by respondent below) do not require a tether. Dombrowski's other twenty claims all specifically require a tether element.

*2. The Lemieux Patent*

The Lemieux patent discloses a "catheter with self-locating needle guard." The Lemieux device includes a mechanism that keeps the needle guard secured over the needle without the use of a tethering device.

In Lemieux's invention, the needle is slotted. A flange inside Lemieux's needle guard falls into that slot when the needle has been withdrawn from the catheter, preventing the needle guard from falling off of the needle.

Lemieux's patent application was filed on July 11, 1988 and was stipulated by the parties below to be prior art to Dombrowski's patent application which was filed on December 27, 1988. However, the disclosure in the Lemieux patent was not publicly available until more than one and a half years later, when the Lemieux patent issued on August 28, 1990.[2]

**C. Petitioner's Accused Products**

Petitioner began work on safety catheter development in 1988. By October 1989, several needle guard concepts had been rejected, including a slotted needle approach similar to Lemieux's invention and Dombrowski's "tethered" needle guard. By December 1989, petitioner had developed the

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[2]Even though it did not issue until after the Dombrowski application was filed, the earlier-filed Lemieux patent qualifies as prior art under 35 U.S.C. § 102(e).

basic design for the accused catheter — more than eight months before the Lemieux patent issued and about a year before the Dombrowski patent issued.

In late 1990, petitioner began clinical trials of its first safety catheter device. As a result of what petitioner learned from those trials, design refinements were introduced into the safety catheter by early summer 1991. In November 1991, petitioner began clinical evaluations of its accused product — which was approved for marketing in June 1992.

**D. Opinions Of Petitioner's Counsel**

In December 1990 and early 1991, petitioner's in-house patent attorney reviewed the Lemieux and Dombrowski patents and concluded that petitioner's basic design did not infringe the claims of those patents. In January and February 1991, that advice was communicated to petitioner's management. In early 1991, petitioner asked that outside patent counsel consider whether the safety catheter design (including certain design refinements), infringed the Lemieux and Dombrowski patents and whether those patents were valid.

In June 1991, outside counsel sent separate written opinions concerning the two patents to petitioner. Those opinions concluded that petitioner's design did not infringe the claims of those patents. The opinions also concluded that, if construed to cover petitioner's design, the patent claims were invalid in light of the prior art.

**E. The Case Below**

1. *Trial*

a. *Petitioner's 35 U.S.C. § 112 Defense*

In November 1993, the case was tried to the Court. Petitioner argued that Dombrowski's "tetherless" claims were not enabled by the Dombrowski patent specification, as

required by 35 U.S.C. § 112, and were thus invalid. Respondent argued that the disclosure in the Lemieux patent would enable one of skill in the art to make a tetherless embodiment of Dombrowski's invention.

In response, petitioner directed the District Court to the rule of *In re Glass*, 492 F.2d 1228, 1232 (CCPA 1974) which holds that an insufficient specification may not be cured by referring to prior art that is published *after* the specification was filed in the Patent and Trademark Office.[3] Because the Lemieux patent was not published until almost two years after Dombrowski was filed, petitioner argued that respondent was precluded from relying on it to cure Dombrowski's lack of enablement.

On July 18, 1994, the Court issued a memorandum opinion holding the Lemieux and Dombrowski patents valid, enforceable and infringed by petitioner's accused safety catheter products. The Court specifically denied petitioner's 35 U.S.C. § 112 defense as to Dombrowski's tetherless claims, holding that:

> As [respondent] has argued, the parties stipulated that the Lemieux '207 Patent is prior art to the Dombrowski invention, and it is not unreasonable to conclude that one of ordinary skill in the art would have had this knowledge when construing Claims 18 and 19 of the Dombrowski Patent (48a).

The Court's opinion mentioned neither *In re Glass* nor the undisputed fact that Lemieux was published *after* Dombrowski's filing date. On April 10, 1995, the Court issued a judgment order permanently enjoining Petitioner from making, using or selling the accused safety catheter devices.

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[3]Decisions of the Court of Customs and Patent Appeals are binding precedent in the Federal Circuit. *South Corp. v. United States*, 690 F.2d 1368 (Fed. Cir. 1982).

b. *Respondent's Assertion That Petitioner's Infringement Was Willful*

At trial, the engineers responsible for developing petitioner's accused safety catheter product testified that the product was developed independently and without copying any feature of either the Lemieux or Dombrowski patent. That testimony was corroborated by documentary evidence.

In determining that "the evidence that [respondent] relies upon in support of a finding of willfulness is rebutted by other evidence adduced at trial by [petitioner] including some opinions of counsel", the District Court made specific note of petitioner's "strenuous" argument that "the device was independently developed" (41a). Nowhere in its opinion did the District Court find that Petitioner copied or adopted features from the Lemieux or Dombrowski patent.

2. *Appeal*

a. *Petitioner's 35 U.S.C. § 112 Defense*

Petitioner appealed several issues to the Court of Appeals for the Federal Circuit, including the District Court's holding concerning the enablement of Dombrowski's tetherless claims under 35 U.S.C. § 112. Petitioner directed the Federal Circuit's attention to that issue in petitioner's briefs and again at oral argument.

On August 12, 1997, the Federal Circuit summarily affirmed the District Court's holdings that the patents in suit are valid and infringed, stating only that: "[a]fter careful consideration, we discern no clear error in the court's findings of fact or error in its conclusions of law" (15a). The Federal Circuit mentioned neither Section 112, *In re Glass* nor the District Court's failure to follow that case.

On August 26, 1997, petitioner moved for a rehearing and suggested a rehearing *en banc* on the enablement issue. The Federal Circuit denied that petition on September 24, 1997.

b. *Respondent's Assertion That Petitioner's Infringement Was Willful*

Respondent cross-appealed the District Court's determination that petitioner's infringement was not willful. In reversing that determination, the Federal Circuit made its own finding of fact that petitioner did not independently develop the accused safety catheters and found that the opinions of counsel on which petitioner relied were not competent. Petitioner also sought a rehearing and suggested a rehearing *en banc* of these findings. The Federal Circuit denied that petition on September 24, 1997.

## REASONS FOR GRANTING THE PETITION

### I.

*Allowing Respondent To Supplement The Dombrowski Specification With Lemieux's Disclosure Violates The Patent Statute*

35 U.S.C. § 131, requires that patent applications be "examined" to ensure their patentability over the existing prior art. The *prima facia* invention date used for that determination is the date on which a patent application is filed in the Patent and Trademark Office. It is, therefore, critical that the patent application evidence that the invention is complete as of that date.

To insure that completeness, 35 U.S.C. § 112, requires that every patent application include a "specification" that enables one of skill in the art to make and use the claimed invention. If the applicant cannot supply sufficient information to enable his claimed invention, he is not yet in a position to apply for those claims. Dombrowski did not supply sufficient information to enable tetherless claims and was not in a position to apply for such claims.

The District Court sanctioned a violation of the patent statute when it allowed respondent to supplement the Dombrowski specification with the disclosure from the Lemieux patent that was not available to the public when the Dombrowski application was filed.

## A. The Patent Statute

During the examination process required by 35 U.S.C. § 131, a Patent Examiner determines, *inter alia,* whether prior art that preceded the applicant's invention "anticipates" it or renders it "obvious" under 35 U.S.C. §§ 102 and 103. The *prima facie* invention date used for this determination is the date on which the application is filed in the Patent and Trademark Office. *In re Argoudelis*, 434 F.2d 1390, 1395 (C.C.P.A. 1970) (J. Baldwin, concurring). As Judge Baldwin explained:

> Because the filing date is so important in determining patent rights, it is essential that there be no question that, at the time an application for patent is filed, the invention claimed therein is fully capable of being reduced to practice (i.e., that no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remain in order to obtain an operative, useful embodiment). *Id.*

The "usual way in which an applicant provides such assurance that this invention has reached the necessary stage of completion" is to provide a full written description and enabling disclosure in accordance with 35 U.S.C. § 112. *Id.*[4]

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[4]A patent applicant can also "show that the invention was complete at the time of filing" by incorporating co-pending patent applications by reference, which must then be made available upon issuance. *In re Hawkins*, 486 F.2d 569, 574 (C.C.P.A. 1973). Where an invention depends on the use of a microorganism not readily available to the public, reference to microorganisms in the application as filed will also

Section 112 requires that the "specification" of a patent application:

> shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

The written disclosure must enable the claimed invention "as of the filing date." *In re Glass*, supra at 492 F.2d at 1232. If enablement depends "on information. . .found in *subsequent* publications," a specification does not evidence a completed invention as filed. *Id.* "Therefore, if the specification is enabling only in light of something that happens after filing, then it does not satisfy section 112." Herbert F. Schwartz, *Patent Law and Practice*, Second Ed. 71 (1995).

Allowing a patent application to be enabled by subsequent information would violate 35 U.S.C. § 132, which prohibits the addition of "new matter" once an application has been filed in the Patent and Trademark Office. *In re Glass*, supra 492 F.2d at 1232. Section 132 thus mandates that an applicant's "disclosure is closed when the patent application is filed. There is no opportunity for an inventor to include subsequent improvements or modifications in an application or patent after filing." *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1534 (Fed. Cir. 1991).

### B. The Decisions Below

In allowing respondent to enable Dombrowski's tetherless claims with information found in a subsequent publication, the District Court sanctioned a violation of the patent

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establish a completed invention. *In re Argoudelis*, 434 F.2d 1390, 1355 (C.C.P.A 1970). However, those microorganisms also must be publicly available upon issuance.

statute. Respondent was allowed to add new matter contrary to the mandate of 35 U.S.C. § 132. That ignores the plain language of the Patent Statute and is contrary to the holding of *In re Glass.*[5]

By failing to deal with this issue, the Federal Circuit allowed a decision to stand that invites patent applicants to ignore the enablement requirements of Section 112 and to circumvent Section 132 by relying on "new matter" from subsequent publications. In these circumstances, the important issue of whether a patentee may enable a claimed invention by referring to prior art published after the patentee's application was filed should be settled by this Court.

## II.

### *The Federal Circuit Misapplied The Clearly-Erroneous Standard Of Appellate Review In Making Its Own Findings Of Fact Concerning The Development Of Petitioner's Catheters*

The standard governing appellate review of a district court's finding of fact is set forth in Rule 52(a), F.R.Civ.P.:

> "[f]indings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses."

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[5]*In re Glass* is entitled to substantial respect, setting forth, as it does, a long standing rule of statutory construction which Congress has not seen fit to alter and on which the courts, the United States Patent and Trademark Office and patent practitioners have relied for over 20 years. *Hilton v. South Carolina Pub. Rys. Comm'n, 502 U.S. 197, 202, 112 S.Ct. 560 (1991).*

As the Court observed in *Anderson v. City of Bessemer City*, 470 U.S. 564, 575, 105 S.Ct. 1504 (1985):

> When findings are based on determinations regarding the credibility of witnesses, Rule 52(a) demands even greater deference to the trial court's findings; for only the trial judge can be aware of the variations in demeanor and tone of voice that bear so heavily on the listener's understanding of and belief in what is said. . . . [W]hen a trial judge's finding is based on his decision to credit the testimony of one of two or more witnesses, each of whom has told a coherent and facially plausible story that is not contradicted by extrinsic evidence, that finding, if not internally inconsistent, can virtually never be clear error.

In this case, the engineers responsible for developing petitioner's safety catheter product testified at trial that the product was developed independently and without copying any feature of the patents-in-suit. The District Court heard that testimony, admitted petitioner's corroborating documentary evidence and considered Critikon's copying arguments. The District Court did not find that petitioner copied or adopted features from the patents-in-suit.

The Federal Circuit discarded the District Court's province as evaluator of witnesses and documentary evidence and, instead, stated that "[i]t must be more than a coincidence that [petitioner] managed to commercialize its design by adopting features disclosed in [the patents-in-suit] soon after it became aware of their existence" (15a). The opinion below does not even claim to make a *de novo* review of actual evidence rather than pure hindsight conjecture.

While petitioner understands that a petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings, the Federal Circuit's disregard of the appropriate standard of appellate review resulted in a

serious error. Petitioner was denied an opportunity for rehearing on this issue by the Federal Circuit and "can now look only to the Supreme Court for correction" of this unjust result. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 88, 113 S.Ct. 1967 (1993) (citation omitted).

## III.

### *The Federal Circuit Misapplied The Standard For Determining Whether An Opinion Of Counsel Is Competent And Reliable*

The Federal Circuit has established the standard to determine whether a patent validity or infringement opinion of counsel is competent and reliable. *Westvaco Corp. v. International Paper Co.*, 991 F.2d 735, 744 (Fed. Cir. 1993). In this case, the Federal Circuit made a blanket statement that the established standard was not met by any of the opinions on which petitioner relied:

> the four opinions are . . . superficial and conclusory in nature. There is no analysis of specific claims, no interpretation of claim language, no discussion of the mean-plus-function claim limitation claim and no meaningful discussion of the prosecution history.

This blanket criticism, however, cannot possibly reflect even a cursory review of the June 11, 1991 opinion petitioner received from its outside counsel concerning the Dombrowski patent (15a).[6]

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[6]Two of the four pre-product introduction opinions that petitioner received relate to the Lemieux patent. Because the Lemieux patent was held by the Federal Circuit to be unenforceable due to respondent's inequitable conduct before the Patent and Trademark Office, we do not address here the Federal Circuit's findings as they apply to the Lemieux opinions.

First, that opinion plainly includes a detailed analysis of the claims of the Dombrowski patent (60a-62a) and a meaningful and focussed discussion of the prosecution history (57a-59a), including the prior art cited by the Patent Examiner (57a-62a). Second, the Federal Circuit's criticism concerning "the means-plus-function claim limitations" cannot possibly apply to that opinion because the asserted claims of the Dombrowski patent do not include any means-plus-function limitations.

Third, the Federal Circuit stated that the "opinions did not discuss the infringing catheter product" (14a). In addition to being unsupported, that finding has no impact on the opinion's conclusion concerning *invalidity*. It is well-established that an opinion of invalidity or an opinion of noninfringement will independently provide a good faith basis to introduce a product. *Graco, Inc. v. Binks Mfg. Co.*, 60 F.3d 785, 792-93 (Fed. Cir. 1995).

The July 11, 1991 opinion of counsel that the Dombrowski patent was invalid and noninfringed is highly competent and fully meets the accepted standard of reliability. Allowing the Federal Circuit's decision to stand would make the application of that standard unpredictable and would create significant confusion regarding the steps a party must take to obtain legal advice before making a decision whether to manufacture and market its products.

## CONCLUSION

For the reasons set forth above, this petition for a writ of certiorari should be granted.

December 23, 1997

Respectfully submitted,

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# APPENDIX

95-1322, 95-1363

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CRITIKON, INC.,
*Plaintiff-Cross Appellant*

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,
*Defendant-Appellant.*

**JUDGMENT**

***ON APPEAL from the*** United States District Court for the District of Delaware

***in Case NO(s).*** 93-108-JJF

***This CAUSE having been heard and considered, it is ORDERED AND ADJUDGED:***

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

ENTERED BY ORDER OF
THE COURT

DATED AUG 12 1997 [SIGNATURE]
Jan Horbaly, Clerk

ISSUED AS A MANDATE: OCTOBER 1, 1997

95-1322, 95-1363

# UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CRITIKON, INC.,

*Plaintiff-Cross Appellant*

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,

*Defendant-Appellant.*

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*DECIDED: August 12, 1997*

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Before ARCHER, Chief Judge; RICH, and MAYER, Circuit Judges.

RICH, Circuit Judge.

## DECISION

Becton Dickinson Vascular Access, Inc. (Becton Dickinson) appeals from the April 10, 1995 judgment of the United States District Court for the District of Delaware, No. 93-108-JJF, issuing a permanent injunction in favor of Critikon, Inc. (Critikon) enjoining Becton Dickinson from making, using, selling or offering to sell its infringing safety catheter products in the United States based on U.S. Patent Nos.4,952,207, reissued as RE34,416, and 4,978,344 (the patents). Following a bench trial, the district court held that: (1) the patents were not invalid; (2) Becton Dickinson had infringed the patents, both literally and under the doctrine of equivalents; (3) the infringement was not willful; (4) Critikon did not engage in inequitable conduct; and (5) Critikon was eligible for injunctive relief. Becton Dickinson appeals the holdings on validity, infringement and inequitable conduct underlying the permanent injunction. Critikon cross-appeals the finding that infringement was not willful. We affirm-in-part and reverse-in-part and remand.

## BACKGROUND

The patents and relevant claims in suit are claims 8, 21, and 56 of U.S. Patent No. RE34,416 (Lemieux reissue patent) and U.S. Patent No. 4,952,207, (original Lemieux patent) and claims 18 and 19 of U.S. Patent No. 4,978,344, (Dombrowski patent). These patents are in the field of intravenous (IV) catheters. IV catheters are thin tubes that are inserted into a vein for the administration of fluids and the like. A needle is used to insert the tube into the vein and then the needle is withdrawn, leaving the tube in the vein. The patents are specifically directed to safety IV catheters, designed to protect health care workers from accidental needle sticks. They feature a needle guard that automatically moves into position over the tip of the needle as the needle is withdrawn from the IV catheter. For ease of reference, we will refer to the reissue and original Lemieux patents collectively as the "Lemieux patents." Claims were added by the reissue.

Through a series of amended complaints, Critikon filed an infringement action against Becton Dickinson based on the Lemieux patents and the Dombrowski patent. The first such complaint alleged infringement of claim 8 of the original Lemieux patent and subsequently included a motion for preliminary injunction to enjoin Becton Dickinson from making, using or selling its catheter product for the pendency of the suit. On July 16, 1993, the district court granted the motion for preliminary injunction based on claim 8 of the original Lemieux patent. Becton Dickinson immediately filed a notice of appeal and moved us to stay the preliminary injunction pending its appeal. On August 26, 1993, we denied that motion.

In the interim, Critikon amended its complaint to assert a claim for infringement of the Dombrowski patent and, subsequently, the Lemieux reissue patent. Further, Becton Dickinson amended its answer to add the defense that the

Lemieux patents were unenforceable because of Critikon's allegedly inequitable conduct during the course of prosecution.

Having obtained a trial date, Becton Dickinson withdrew its appeal to us of the preliminary injunction and, on November 1, 1993, the parties commenced a two week bench trial on liability and damages issues. The district court issued a Memorandum Opinion on July 18, 1994, finding, inter alia, that Becton Dickinson's catheter products infringed claims 8, 21, and 56 of the Lemieux patents and claims 18 and 19 of the Dombrowski patent. Further, the district court held the patents valid and enforceable. Critikon moved for a permanent injunction, and, on April 10, 1995, the district court issued the order enjoining Becton Dickinson that is the subject of this appeal.

## DISCUSSIONS

### 1. Infringement/Validity

We review a district court's judgment for errors of law and clearly erroneous findings of fact. Fed. R. Civ. P. 52(a). The district court found the patents-in-suit not invalid and infringed, both literally and under the doctrine of equivalents. After careful consideration, we discern no clear error in the court's findings of fact or error in its conclusions of law and affirm the district court's findings of no invalidity and infringement.

### 2. Inequitable Conduct

On appeal, Becton Dickinson argues that Critikon's failure to disclose U.S. Patent No. 4,834,718 (the McDonald patent) during both the prosecution of the original Lemieux patent and the Lemieux reissue patent constituted inequitable conduct. Becton Dickinson argues that the district court's failure to find intent is contrary to the weight of the

evidence. We agree. We hold that the McDonald patent was material to patentability and Critikon should have disclosed it to the Patent and Trademark Office (PTO). But, more importantly, during the reissue proceedings, Critikon should have disclosed that the original Lemieux patent was concurrently involved in the present litigation and that claims of invalidity and inequitable conduct were asserted against the patent. Failure to disclose the McDonald patent and the fact that the Lemieux patent was in litigation was done with an intent to mislead or deceive and rises to the level of inequitable conduct.

A determination of inequitable conduct is committed to a district court's discretion. Accordingly, the court's ultimate determination is reviewed for abuse of discretion; the subsidiary factual questions are reviewed for clear error and are not to be disturbed unless we have a definite and firm conviction that a mistake has been committed. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1215, 18 USPQ2d 1016, 1028 (Fed. Cir. 1991).

A patent applicant's duty to disclose material information to the PTO arises under the general duty of candor, good faith, and honesty embodied in 37 C.F.R. § 1.56(a) (1996). Specifically, applicants have a duty to disclose to the PTO information of which they are aware which is material to the examination of the application. 37 C.F.R. § 1.56(a) (1996). This duty is also applicable to reissue proceedings. 37 C.F.R. § 1.175(a)(7) (1996).

However, a breach of the disclosure duty alone does not render the patent unenforceable. There must be a showing of inequitable conduct. Inequitable conduct resides in the failure to disclose material information with an intent to deceive or mislead the PTO. *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1559-60, 223 USPQ 1089, 1092 (Fed.Cir. 1985). Once thresholds of materiality and intent have been established, the court conducts a balancing test

and determines whether the scales tilt to a conclusion that "inequitable conduct" occurred. *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440, 17 USPQ2d 1834, 1839 (Fed. Cir. 1991). The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa. Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986).

A. Intent

Becton Dickinson argues that the district court ignored the weight of the evidence in holding that Becton Dickinson failed to establish by clear and convincing evidence that the Lemieux patents were unenforceable due to inequitable conduct. Our review of the record leads us to conclude that Critikon failed to cite the McDonald patent and to disclose the ongoing litigation to the PTO with intent to mislead or deceive. Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances. *J.P. Stevens*, 747 F.2d at 1560, 223 USPQ at 1092. For example, intent may be inferred where a patent applicant knew, or should have know, that withheld information would be material to the PTO's consideration of the patent application. *Driscoll v. Cebalo*, 731 F.2d 878, 885, 221 USPQ 745, 751 (Fed. Cir. 1984).

A relatively high degree of intent may be inferred under the facts of this case. Critikon was aware of the McDonald Patent. It was aware that the "retaining means" was a point of novelty the examiner relied upon during the course of prosecution. It knew or should have known that the "retaining means" disclosed in the McDonald patent was relevant to a point of novelty in the Lemieux proceedings. And, despite this, it did not disclose the patent or provide a good faith explanation for not disclosing the patent. Furthermore,

despite the clear materiality of the ongoing litigation to the reissue proceedings, Critikon never disclosed its existence to the PTO.

Critikon was intimately familiar with the McDonald patent. Both of Critikon's patent counsel who were involved in the prosecution of the Lemieux patents, Mr. Colletti and Mr. York, had reviewed the McDonald patent in detail. On appeal, Critikon argues that Mr. Colletti believed that the reference was not material and that Mr. York had no recollection of the patent. However, at one point Mr. York reviewed the McDonald patent and in handwritten annotations opined that all the claims, except those including the "retaining means," were invalid. Further, there is evidence that he passed these notes on to Mr. Colletti, who cited the McDonald patent to the PTO in several other patent proceedings. If that were not sufficient to infer intent to mislead or deceive, the record indicates that Critikon's counsel was repeatedly confronted with the McDonald patent and its significance over the course of the litigation, which substantially overlapped the Lemieux reissue proceedings.

Critikon knew that the examiner considered the retaining means a point of novelty of the Lemieux patent. The examiner was in direct communication with Critikon and reiterated on at least two occasions the importance of the "retaining means" as a point of novelty in the application. During the course of prosecution of the original Lemieux patent, the examiner twice rejected the application's independent claims that did not call for a means for retaining the needle guard together with the catheter hub. Both times, the examiner stated that those claims "lack the structure at the point of novelty to achieve the intended result and are therefore incomplete," and suggested that they be amended to include retaining means for holding the needle guard within the catheter hub until the needle guard was engaged in place over the needle tip. Critikon was aware of the PTO

procedures in effect at that time, which required examiners to construe means-plus-function claim limitations broadly to encompass any means for performing the function recited in the means clause.

Contrary to the district court's conclusion and Critikon's argument, Critikon's counsel made no effort to offer a good faith explanation of why McDonald was never cited, but merely offered conclusory statements that the reference was cumulative. The court stated that it "weighed the testimony of both Mr. Yorks and Mr. Colletti and determined that their explanations for not disclosing the McDonald '718 patent were credible under the totality of the circumstances." However, the court does not identify the testimony it relied upon. Our review of the record does not reveal a single instance where Mr. Yorks or Mr. Colletti provided a good faith explanation for the exclusion.

Further, the district court did not address Critikon's failure to disclose the ongoing litigation to the PTO. As evidenced by their participation in depositions, the patent counsel who were handling the reissue proceedings were keenly aware of the litigation and the issues involved prior to the resolution of the reissue proceedings. However, there is no evidence in the record that anyone reported the ongoing litigation to the PTO. Nor is there any evidence as to a good faith explanation as to why it was never reported.

It is axiomatic that "[c]lose cases should be resolved by disclosure, not unilaterally by applicant." *Labounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076, 22 USPQ2d 1025, 1033 (Fed. Cir. 1992). This sentiment is also repeatedly reflected in the Manual of Patent Examining Procedure (MPEP), which, although it does not have the force of law, is well known to those registered to practice in the PTO and reflects the presumptions under which the PTO operates. See *Refac Int'l Ltd. v.*

*Lotus Development Corp.*, 81 F. 3d 1576, 1584 n.2, 38 USPQ2d 1665, 1671 n.2 (Fed. Cir. 1996).

> Presumably, applicants will continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive.

MPEP 2001.04 (1994).

No single factor or combination of factors can be said always to require an inference of intent to mislead; yet a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish "subjective good faith" sufficient to prevent the drawing of an inference of intent to mislead. A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415, 5 USPQ2d 1112, 1116 (Fed. Cir. 1987).

B. Materiality

Information must be disclosed when it is material to patentability. The starting point in determining materiality is the definition of the PTO, which recites, in part, as follows: "information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and . . . [i]t refutes, or is inconsistent with, a position the applicant takes in: . . . [a]sserting an argument of patentability." 37 C.F.R. 1.56 (b)(2)(ii) (1996).

The district court found the McDonald patent was not material because it was substantially different from the

claimed invention. The court was "persuaded by the testimony of both expert witnesses that the McDonald [ ] patent teaches a device that is substantially different than that contemplated by the Lemieux patents." However, the court did not explicitly outline the evidence that it relied upon in drawing this conclusion nor did it address Critikon's failure to disclose the ongoing litigation during the Lemieux reissue proceedings.

The court apparently failed to recognize that although overall the Lemieux device may be substantially different from McDonald, the McDonald patent teaches two features, which the examiner considered central in the prosecution of the Lemieux patents. Briefly, the protective housing of the McDonald device is designed to automatically cover the needle tip for the purpose of preventing accidental needle sticks. The housing is comprised of a long barrel and a guard hub. As the needle is withdrawn from the catheter, the proximal end of the housing engages with a groove on the handle and automatically releases the needle guard that sheaths the needle. Specifically, it teaches a "retaining means" and an automatically, albeit passively, engaged protective housing.

As noted above, the examiner specifically relied on the "retaining means" as a point of novelty. The use of the "retaining means" to achieve automatic positioning is disclosed only in the uncited McDonald patent; it is not disclosed in any other prior art considered by the examiner. Furthermore, there was testimony from Mr. Fischell, Becton Dickinson's expert, to the effect that the McDonald patent is the most relevant art to the "retaining means" limitation.

Specifically, Mr. Fischell indicated that the retaining means were integral to the automatic positioning. In addition, Mr. Fischell indicated that the key features of McDonald were the automatic positioning and the "retaining means." Mr. Colletti reflected this position, and Critikon's

knowledge thereof, when he testified that he could not recall any prior art considered by the examiner who allowed the original Lemieux patent that describes a catheter device with the "retaining means." And yet Mr. Colletti relied on the novelty of the "retaining means" and the automatic positioning of the protective housing in his arguments to gain allowance of the patent application. It would appear that the "retaining means" and the automatic positioning aspects of McDonald would have been material to a reasonable patent examiner under the PTO standard.

Critikon argues that the McDonald device is significantly different for three primary reasons: (1) the McDonald device operates differently; (2) the McDonald device does not feature automatic positioning; and (3) the McDonald device requires a two step procedure while the Lemieux patent requires the protective housing to function without intervention. The first reason is of no moment. A device that operates differently, assuming the McDonald patent operates differently, may nonetheless have relevant features. With regard to the second and third reasons, there is unrefuted testimony that the catheter may be inserted with one hand and, furthermore, the Lemieux patent only requires that the catheter function without intervention in its preferred embodiment. Thus, we find Critikon's arguments without merit.

The district court did not consider whether the litigation relating to the Lemieux patents was material to the Lemieux reissue proceedings. A patent applicant's duty to disclose is not limited to disclosing prior art. A patent applicant must disclose any material information to the PTO. 37 C.F.R. § 1.56(a) (1996). There seems little doubt that the litigation involving the patent in question would be relevant to its reissue proceeding. According to the Manual of Patent Examining Procedure, relevant litigation includes the defenses raised against validity of the patent, or charges of

fraud or inequitable conduct in litigation, which would normally be material to the reissue application. MPEP 2001.06(c) (1994).

> Where the patent for which reissue is being sought is, or has been, involved in litigation which raised a question material to patentability of the reissue application, such as the validity of the patent, or any allegations of "fraud", "inequitable conduct", or "violation of duty of disclosure", the existence of such litigation must be brought to the attention of the Office by the applicant. . . . [T]he defenses raised against validity of the patent, or charges of "fraud" or "inequitable conduct" in the litigation, would normally be "material to patentability" of the reissue application. . . . As a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and /or "fraud", or "inequitable conduct" relating to the original patent, and the nature of the litigation materials relating to these issues.

MPEP 2001.06(c) (1994); *see also,* MPEP 1442.04 (1994). In the interests of consistent claim interpretation, it may be appropriate to suspend such proceedings until such litigation is resolved.

In summary, Critikon failed to disclose the McDonald patent, which it should have known was material, but, more importantly, it failed to disclose the ongoing litigation in the reissue proceedings. Given the materiality and the failure at any point to offer a good faith explanation of the pattern of nondisclosure, an intent to mislead may be inferred. We reverse the district court's finding with regard to inequitable conduct and hold the original Lemieux patent and the Lemieux reissue patent unenforceable.

3. Willful Infringement

The district court's finding that infringement was not willful is one of fact, and subject to the "clearly erroneous" standard of review. *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1459, 18 USPQ2d 1842, 1847 (Fed. Cir. 1991). We must determine whether the district court clearly erred in finding that Critikon failed to meet its burden of proving willfulness by clear and convincing evidence. *BIC Leisure Prods., Inc. v. Windsurfing Int'l Inc.*, 1 F.3d 1214, 1222, 27 USPQ2d 1671, 1678 (Fed. Cir. 1993). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948); *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 926 F.2d 1161, 1164, 17 USPQ2d 1922, 1925 (Fed. Cir. 1991). After careful review of the record, we hold that the district court clearly erred in finding that infringement was not willful.

The district court based its determination that there was no willful infringement on the finding that, while Becton Dickinson may have been aware of Critikon's patents and the potential for infringement, it reasonably relied on opinion of counsel, it could have independently developed the infringing catheter product, and the field was rapidly developing. On appeal, Critikon argues that while the court correctly found that Becton Dickinson was "imprudent" and "less than cautious", it erred in its ultimate conclusion of nonwillfulness.

Becton Dickinson argues that it relied in good faith on eight separate written opinions of counsel. The eight opinions, obtained between January 1991 and August 1993, each reiterated that the infringing catheter product did not infringe the claims of the Lemieux or Dombrowski patents. Only four of these opinions were received prior to placing

the infringing catheter product on the market in the fall of 1991. Critikon correctly argues that the district court could only rely on those four opinions received prior to marketing its infringing catheter product in determining the reasonableness of Becton Dickinson's actions. *Underwater Devices v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1390, 219 USPQ 569, 576-77 (Fed. Cir. 1983).

These four opinions did not discuss the infringing catheter product. Rather, they relate to a short-nosed device that was eventually discarded by Becton Dickinson. In the short nosed device, no physical contact occurs between the nose and the catheter hub, thus, it might reasonably fall outside the scope of the claims of both the Lemieux patents and the Dombrowski patent. Before commercialization, Becton Dickinson apparently shifted to the long nose design when the short nosed design proved dangerous and commercially unacceptable. Significant design changes, in most instances, would require a new opinion of counsel. *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988).

In addition to relating to the short-nosed catheter, the four opinions are, as Critikon argues, superficial and conclusory in nature. There is no analysis of specific claims, no interpretation of claim language, no discussion of the means-plus-function claim limitations and no meaningful discussion of the prosecution history.

Critikon further argues that the district court erred by failing to recognize that Becton Dickinson adopted features from the Lemieux and Dombrowski patents. We agree that the court appears to have overlooked overwhelming evidence in the record that Becton Dickinson's efforts to develop a safety catheter were a failure. In 1991, Becton Dickinson engineers could not precisely identify the problems associated with their device. Becton Dickinson asserts that it finalized the basic device by December 1989, and yet Becton Dickinson's engineers were reporting that

there is "no doubt that the results are extremely negative" over a year later. It must be more than coincidence that Becton Dickinson managed to commercialize its design by adopting features disclosed in the Dombrowski patent and the Lemieux patents soon after it became aware of their existence.

Based on the record before us, we hold that the district court clearly erred in finding that Becton Dickinson was not willfully infringing the claims of the Dombrowski patent and the Lemieux patents. Becton Dickinson had knowledge of the patents in suit, used this knowledge to develop its own commercial model, and demonstrated utter disregard for the need to obtain competent legal advice. The fact that moving products from development to commercialization is a rapid process is insufficient rationalization to warrant this conduct. Clearly Becton Dickinson had the opportunity to obtain four opinions of counsel before marketing the infringing product. Thus, we must conclude that the district court clearly erred in not finding willful infringement.

## CONCLUSION

In conclusion, we affirm the district court's holding that the Lemieux patents and the Dombrowski patent are not invalid and infringed. We reverse the court's holding that the Lemieux patents are enforceable and hold them unenforceable because of inequitable conduct. We reverse the holding that infringement was not willful. We remand to the district court for further proceedings in accordance with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

95-1322, 95-1363

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CRITIKON, INC.,
*Plaintiff-Cross Appellant*
v.
BECTON DICKINSON VASCULAR ACCESS, INC.,
*Defendant-Appellant.*

*Harry J. Roper*, Roper & Quigg, of Chicago, Illinois, argued for plaintiff/cross-appellant. With him on the brief was *George S. Bosy*. Of counsel on the brief was *Madonna M. Malin*, Johnson & Johnson, of New Brunswick, New Jersey. Of counsel was Ellen D. Law, Roper & Quigg.

*Edward F. Mullowney*, Fish & Neave, of Palo Alto, California, argued for defendant-appellant. With him on the brief was Richard M. Barnes, Fish & Neave, of New York, New York. Of counsel on the brief was Leslie Gorden Fagen, Paul, Weiss, Rifkind, Wharton & Garrison, of New York, New York.

Appealed from : U.S. District Court for the District of Delaware.

Judge Farnan, Jr.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF
JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED:
08/12/97

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing in banc. The questions and answers are those frequently answered by the Clerk's Office.

No costs were taxed in this appeal.

Exhibits and visual aids shall be promptly retrieved by the party that lodged them with this court.

JAN HORBALY
*Clerk*

cc: EDWARD F. MULLOWNEY
HARRY J. ROPER

CRITIKON INC. V BECTON DICKINSON, 95-1322, 95-1363
DCT — 93-108

Civil Action No. 93-108-JJF

UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

CRITIKON, INC.,

*Plaintiff.*

v.

BECTON DICKINSON VASCULAR: ACCESS, INC.,:

*Defendant.*

Arthur G. Connolly, Jr., of CONNOLLY BOVE LODGE & HUTZ, Wilmington, Delaware. Harry J. Roper, George S. Bosy, Raymond N. Nimrod, and Ellen D. Law, of ROPER & QUIGG, Chicago, Illinois. Donna M. Malin, of JOHNSON & JOHNSON, New Brunswick, New Jersey. Attorneys for Plaintiff.

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**MEMORANDUM OPINION**

July 18, 1994
Wilmington, Delaware

FARNAN, District Judge.

The parties in this patent dispute are the Plaintiff Critikon, Inc. ("Critikon") and the defendant Becton Dickinson Vascular Access, Inc. ("Becton Dickinson"). In July, 1993, the Court granted Critikon's Motion for a Preliminary Injunction and enjoined Becton Dickinson from the further manufacture and sale of Becton Dickinson's accused Saf-T-Cath™ brand of safety catheters which are the accused devices and the subject of this patent infringement litigation. Becton Dickinson initially appealed the injunction order. However, Becton Dickinson later dismissed the appeal after the Court of Appeals for the Federal Circuit refused to stay the injunction pending appeal. The parties then proceeded to trial in November of 1993 on both liability and damage issues and thereafter submitted briefs in support of their respective positions. This Opinion shall constitute the Court's Findings of Fact and Conclusions of Law as required by Federal Rule of Civil Procedure 52.

## I.

## BACKGROUND

Because the Court set forth a substantial amount of background information in the July 16, 1993 Opinion granting the preliminary injunction, the Court will abbreviate the present background presentation where appropriate. When Critikon brought this action on March 1, 1993, it asserted infringement of United States Patent No. 4,952,207 issued to Francis P. Lemieux ("the Lemieux '207 Patent"). On April 1, 1993, Critikon added to its Complaint an assertion that the accused devices also infringe United States Patent No. 4,978,344 ("the Dombrowski Patent"). After the Patent and Trademark Office ("PTO") granted a reissue of the Lemieux '207 Patent on October 19, 1993, Critikon again amended its Complaint to assert infringement of the reissued Lemieux Patent, United States Patent No. RE34,416

("the Lemieux Reissue Patent"). For ease of reference the Court will simply refer to the collective Lemieux Patents as "the Lemieux Patents." Critikon presently claims that the accused devices manufactured by Becton Dickinson infringe Claims 8, 21 and 56 of the Lemieux Patents and Claims 18 and 19 of the Dombrowski Patent.

The technology of intravenous catheters, also known as I.V. catheters, is relatively straightforward. I.V. catheters are primarily used to administer fluids, sometimes containing medications, directly into a patient's vascular system. The catheter is inserted into a patient's vein by a health care professional by using a handheld installing apparatus which includes a sharp tip needle. The needle is positioned in the interior hollow portion of the catheter with its tip extended slightly beyond the edge of the catheter. The end of the apparatus opposite the needle tip is made up of needle connected to a needle hub which is capable of being held by the health care worker during the insertion procedure.

The insertion procedure contains four basic steps: (1) the health care worker inserts the needle and catheter together into the patient's vein; (2) after insertion into the vein with the needle point, the catheter is forwarded into the vein of the patient by the health care worker pushing the catheter with his or her finger; (3) the health care worker withdraws the needle by grasping the "hub" end (opposite the point end) while at the same time applying pressure to the patient's skin at the insertion sight with his or her free hand; and (4) the health care worker then tapes the now inserted catheter to the patient's skin and connects the exposed end of the catheter, called the catheter hub, to the source of the fluids to be administered.

The problem is that immediately after the withdrawal of the needle from the patient's vein, the health care professional who is involved in at least two urgent procedures must place the exposed needle tip at a nearby location and

address the tasks required to accomplish the needle withdrawal. It is at this juncture that the exposed needle tip creates a danger of an accidental needle stick occurring, which under the circumstances, leaves the health care worker vulnerable to the transmission of various, dangerous blood born pathogens, including AIDS, hepatitis, etc. It is this danger to the health care worker from accidental needle sticks that was the impetus for the safety catheter invention.

## II.

## INFRINGEMENT

Infringement occurs when someone "without authority makes, uses or sells any patented invention within the United States during the term of the patent. . . ." 35 U.S.C. § 271 (1988). Plaintiffs are required to prove infringement by a preponderance of the evidence.

The determination of whether the a accused device infringes the asserted claims of the patents in suit involves a two-step process. *Autogiro Co. of America v. United States*, 384 F.2d 391, 401 (Ct. Cl. 1967); *Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F. 2d 902, 908 (Fed. Cir. 1988). First, the Court must determine the scope of the patent claims in issue by construing the language of those claims. *Autogiro*, 384 F.2d at 401; *Grain Processing*, 840 F.2d at 908. Second, once the Court has established the meaning of the asserted claims, the Court must then compare those claims with the accused device to determine whether the accused device infringes the patent, either literally or under the doctrine of equivalents. *Autogiro*, 384 F.2d at 401; *Grain Processing*, 840 F.2d at 908.

When interpreting a disputed term in a claim, courts look to several factors which include: (1) the literal language of the claims; (2) the patent specification; (3) the prosecution history; and (4) expert testimony on how those skilled in the

art would interpret the claim. *Loctite Corp. v. Ultraseal, Ltd.*, 781 F.2d 861, 867 (Fed. Cir. 1985); *McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 672-75 (Fed. Cir.), *cert. denied*, 496 U.S. 1037 (1984).

## A. THE LEMIEUX PATENT

The Lemieux Patent is directed to an intravenous catheter with a needle guard that encloses or encases the tip of the I.V. catheter needle as the needle is being withdrawn from the catheter once the catheter has been placed in a patient's vein.

### 1. Claim 8 of the Lemieux Patents

#### a. Claim Interpretation

The Court interprets Claim 8 as follows:

1. The Claim requires a needle guard that is self-locating, which means it is automatically positioned over the tip of the needle after the needle is withdrawn from the catheter subsequent to placement of the catheter in the patient's vein.

2. The Claim requires a catheter assembly which is a catheter attached to a catheter hub. The catheter assembly permits one end of the catheter to be inserted into a patient's vein and the other end of the catheter into a catheter hub which is ultimately secured to an external device for the introduction of fluids into the patient.

3. The Claim requires an introducer needle assembly which is comprised of a needle and a needle hub. The needle hub is the portion of the catheter assembly that is utilized by the health care worker.

4. The Claim requires that the needle assembly be comprised of a hollow needle that is attached at its proximal end to a needle hub that extends distally exposed from the distal end of the needle hub.

5. The Claim requires a means located at the distal end of the needle, i.e., the sharp tip of the needle, for engaging the needle guard as the needle is withdrawn from the patient's vein.

6. The Claim requires a needle guard that is initially positioned around the needle at the distal end of the needle hub and capable of axial movement relative to the needle.

7. The Claim requires that the needle guard contains a means in its proximal portion for engaging the corresponding means found on the needle and a distal portion of the needle guard that covers the needle tip once the needle guard is engaged with the engaging means.

8. The Claim requires a means for retaining the needle guard in its initial position within the catheter hub by the engagement of the engagement means on the needle and the engagement means on the needle guard.

b. Literal Infringement

The Court finds that Critikon has established by a preponderance of the evidence that the accused safety catheters marketed by Becton Dickinson incorporate each of the elements of Claim 8 of Lemieux Patents, and thus the Court concludes that the Becton Dickinson safety catheters literally infringe Claim 8. (Pl. 's Exs. 106, 410, 418; Def.'s Ex. 183).

Element 1. The Becton Dickinson device is an I.V. catheter with a self-locating needle guard. (Tr. at 76). It is clear that the needle guard automatically positions itself over the distal tip of the needle and the needle is withdrawn from the patient's vein without any additional manipulation on the part of the health care worker.

Element 2. The Becton Dickinson device contains a catheter assembly comprising a hollow catheter tube attached to a catheter hub. (Tr. at 77).

Element 3. The accused Becton Dickinson safety catheter contains a needle assembly for connection with the catheter assembly. (Tr. at 77).

Element 4. An inspection of the Becton Dickinson needle assembly reveals that a hollow needle attached at the proximal end to the needle hub extends distally exposed from the distal end of the needle hub.

Element 5. This element in Claim 8 is written as a "means plus function" limitation. A claim written in "means plus function" language is literally infringed if the accused device performs the identical function recited in the claim by using the same or interchangeable structure to that disclosed in the specification. *Valmont Indus., Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1041-42 (Fed. Cir. 1993).

The Becton Dickinson accused device has a means, located on the distal tip of its needle, of engaging the needle guard. The means is a bump near the needle's distal tip which the Court finds performs the identical function as specified in Claim 8, namely, to engage the needle guard. The bump on the tip of the needle of the accused device is structurally equivalent to the notch described in the Lemieux Patents. (Tr. at 79-81; Pl.'s Ex. 413). *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, Civ. A. No. 93-108-JJF, at *5 (D. Del. July 16, 1993).

Element 6. The needle guard is initially positioned around the needle at the distal end of the needle hub and is capable of axial movement around the needle.

Element 7. As in Element 5, this element is written as a "means plus function" limitation. The needle guard in the Becton Dickinson accused device has a means in its proximal portion for engaging the means, i.e., the bump of the needle shaft. This means performs the identical function specified in Claim 8 of the Lemieux Patents and is

equivalent to the notch structure described in Lemieux Patents. (Tr. at 82). See id.

Element 8. This element is also a means plus function limitation. The Becton Dickinson accused device has a means to ensure that the needle guard remains fixed at the base of the catheter hub while the needle is being withdrawn from the catheter until the needle engages the needle guard. The structure of the Lemieux Patents which performs this function is a split-locking flange which retains the needle guard within the catheter hub through frictional and mechanical contact. The needle guard presses against the inside of the catheter hub until the needle engages with the needle guard. At trial, Critikon's expert testified that the needle guard in the Becton Dickinson accused device is likewise held in place within the catheter hub by a frictional and mechanical force, i.e., by fingers which extend from the needle guard over the catheter hub. (Tr. at 87). The Court finds that the "fingers" structure utilized in the Becton Dickinson device is structurally equivalent or interchangeable with the structure described in the Lemieux Patents. In resolving this last "means plus function" language issue, the Court reviewed the substantial argument set forth by Becton Dickinson at pages 18-37 of its Post-Trial Brief (D.I. 237) and specifically considered the language of 35 U.S.C. § 112, ¶ 6. In resolving the conflict as to whether or not the means employed by the accused device were the structural equivalence of limitations set forth in the Lemieux Patents, the Court was persuaded in its analysis by the testimony of Critikon's expert, Mr. Vaillancourt, and by the fact that the testimony of Becton Dickinson's expert, Mr. Fischell, provided only limited opposition to Mr. Vaillancourt's strong

testimony. A typical example of Mr. Fischell's ambivalence is found at pages 1086 through 1087 of the Trial Transcript:

> Q Now, you will agree with me, won't you, that when those two are separated, then there is also a frictional force involved?
>
> A You mean when they are held in two different hands?
>
> Q No.
>
> As they are being separated, the portion with the slanting lines going from top left to bottom right moves to the right; correct?
>
> A Well, I'm not sure about — you need not describe the mechanics of it.
>
> When it is being pulled apart, there are times when friction is involved.
>
> Q So in the operation of that, there is both mechanical interferences and friction; correct?
>
> A No, not in the retaining operation.
>
> Q But as it is released, there is both a mechanical interference and frictional forces; correct?
>
> A No.
>
> As soon as the device is fully — as soon as the flange there is under the flap of the finger, it is purely frictional. It converts to frictional.
>
> Q So we have it, when you are talking about the flap, you are talking about the portion that i[s] just above the dimensions .060 plus or minus .003?
>
> A Correct.
>
> Q At the point we see it, it is mechanical. Is that your testimony?

A When it is being retained, it is mechanical.

Q Now, in between when it is on the slope line, it is both mechanical and friction, isn't it?

A Yes.

Q Thank you.

(Tr. at 1086-87).

In sum, considering the expert testimony offered by each party and the Court's inspection of the various relevant exhibits, the Court finds that the "means plus function" elements of Claim 8 are equivalently found in the Becton Dickinson accused device.

c. Doctrine of Equivalents

Infringement under the doctrine of equivalents occurs when the alleged infringer's device performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed invention. *Graver Tank & Mfg. Col. v. Linde Air Prods. Co.*,339 U.S. 605, 608 (1950); *Miles Lab., Inc. v. Shandon, Inc.*,997 F.2d 870, 876 (Fed. Cir. 1993), *cert. denied,* 114 S. Ct. 943 (1994). As the Court has previously concluded in its July 16, 1993 Preliminary Injunction Opinion, the Becton Dickinson device performs the same function to achieve the same result as Claim 8 of the Lemieux Patents. See *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.,* Civ. A. No. 93 -108 -JJF, at *6 (D. Del. July 16, 1993). Both the accused device and the invention of Claim 9 operate in the same way, with a self-locating needle guard which moves into position passively — without intervention by the health care worker — as the needle is removed from the vein of the patient. Lastly, both achieve the same result, protection of health care workers and others from accidental needle sticks.

2. Claim 21 of the Lemieux Reissue Patent

a. Claim Interpretation

After reviewing Claim 21 together with the other claims and the specification of the Lemieux Reissue Patent, the relevant prior art, and the testimony of expert witnesses, the Court reads Claim 21 to require the following:

1. The Claim requires a catheter assembly, including a catheter, catheter hub and needle installing unit.

2. The Claim requires a catheter hub which can be utilized to connect the catheter to a source for administering fluids and/or medication to the patient.

3. The Claim requires a hollow tube catheter attached to the catheter hub.

4. The Claim requires a needle hub for connection to a needle.

5. The Claim requires a needle with a sharp point distal tip and a proximal end attached to the needle hub and a first means for engaging the needle guard.

6. The Claim requires a needle guard with a second means on its proximal portion for engaging the first engaging means on the needle and a distal portion able to cover the tip of the needle when the needle and the needle guard are engaged.

7. The Claim requires a means for permitting the catheter hub to remain attached to the needle guard prior to any engagement of the first engaging means on the needle and the second engaging means on the needle guard.

8. The Claim requires a needle guard that is first located between the needle hub and the catheter hub, both of which may be insertable or slidable on the needle.

9. The Claim requires a needle guard positioned between the catheter hub and the needle hub which may slide on the needle until the needle and the needle guard are engaged.

b. Literal Infringement

The Court finds that the Becton Dickinson accused device literally infringes all elements of Claim 21. The Court will review each element of Claim 21 separately with respect to infringement:

Element 1. The Becton Dickinson accused device is a catheter system. (Tr. at 89).

Element 2. The accused device contains a catheter hub. (Tr. at 90).

Element 3. The catheter hub is attached to the catheter.

Element 4. The accused device has a needle hub.

Element 5. This is a "means plus function" limitation requiring that the accused device have a needle with a first means on it for engaging a needle guard at the distal end of the needle. In the accused device there is a bump on the needle which the Court finds performs the same function as that specified, i.e., to engage the needle guard. The Court finds that the bump on the accused device is the structural equivalent of what is disclosed in the Lemieux Reissue Patent because both structures mechanically engage the needle guard thus preventing it from falling off the tip of the needle. (Tr. at 90-91).

Element 6. Like Element 5, this element expresses a "means plus function" limitation. The accused device contains a needle guard having a second means at its proximal portion for engaging the first means on the needle as well as a distal portion for covering the needle tip on the first and second means engaged. This second means located on the

needle guard of the accused device is an aperture in the proximal portion with the diameter smaller than the diameter of the bump on the needle. The Court finds that the aperture performs the identical function described in Claim 21, specifically it engages a corresponding means on the needle. In the Lemieux Reissue Patent, this structure is a split-locking flange which mechanically engages the slot on the needle. The Court finds that an aperture in the accused device and the split-locking flange of the Lemieux Reissue Patent are structurally equivalent in that both involve a mechanical engagement between their respective needle guards and needle which prevent the needle guard from falling of the tip of the needle. (Tr. at 92-95).

Element 7. Like Elements 5 and 6, this also is a "means plus function" limitation. The required function of this element is to attach the catheter hub to the needle guard prior to engagement of the first means on the needle and the second means on the needle guard. In the accused device, the Court finds the needle guard is retained within the catheter hub by the frictional and mechanical contact of fingers which extend from the needle guard over the catheter hub. In the Lemieux Reissue Patent, this function is performed by a split-locking flange which utilizes frictional and mechanical contact. In sum, the Court finds that both structures perform the same function through frictional and mechanical contact and therefore finds that the means utilized by the accused device is structurally equivalent to the means disclosed in the Lemieux Reissue Patent. (Tr. at 95-96).

Element 8. The accused device has a needle guard positioned between the needle guard and the catheter hub and all are insertable or are slidable on the needle.

Element 9. The accused device permits the corresponding engaging means on the needle and on the needle guard

to engage by virtue of a catheter and needle guard which are slidable relative to the needle.

c. Doctrine of Equivalents

As with Claim 8 of the Lemieux Patents, the accused device and the invention of Claim 21 perform substantially the same function, in substantially the same way, to achieve substantially the same result. Both have a needle that utilizes a change in contour on it for engaging a needle guard which is self-locating and engages the needle tip as the needle is removed from the patient's vein when withdrawn through the required catheter. The result of using both Claim 21 and the accused device is that health care workers are protected from accidental needle sticks. (Tr. at 108-09).

3. Claim 56 of the Lemieux Reissue Patent

a. Claim Interpretation

The Court interprets Claim 56 to require the same Elements 1 through 8 as Claim 21. However, the Court reads Claim 56 to require the following additional elements:

9. The Claim requires the needle to be slidable relative to the catheter and the needle guard.

10. The Claim requires that a portion of the needle guard where the second means is located have an inner diameter smaller than the first means which is located have an inner diameter smaller than the first means which is located on the needle so as to permit the two means to engage upon contact and thus prevent the needle guard from falling off the tip of the needle. (Tr. at 107-08; Pl.'s Ex. 61).

b. Literal Infringement

The Court finds that Critikon has established by a preponderance of the evidence that each of the ten elements of Claim 56 are found in the Becton Dickinson accused device.

Elements 1 through 8. These elements are identical to the elements of Claim 21 and the Court reaches the same findings as it did previously.

Element 9. The Court finds that the accused device has a catheter and needle guard which is slidable relative to the needle so as to permit the needle to be partially removed prior to the engagement of the bump on the needle with the aperture of the needle guard. (Tr. at 106-07; Pl.'s Ex. 417).

Element 10. The Court finds that there is a portion of the needle guard of the accused device with a diameter smaller than the bump that is present on the needle so that when the bump and the aperture of the needle guard engage they prevent the needle guard from moving off the tip of the needle.

c. Doctrine of Equivalents

As with Claims 8 and 21, the Court finds that the Becton Dickinson accused device and the invention of Claim 56 operate in substantially the same way to perform substantially the same function to obtain substantially the same result. Specifically with regard to Claim 56, the Court finds that both the invention of Claim 56 and the accused device utilize a self-locating needle guard which engages the needle tip as the needle is withdrawn from the patient's vein through the catheter. This is accomplished by the needle having a changing contour which permits it, upon withdrawal, to engage the needle guard. The result is that once the needle guard is engaged, health care workers are protected from accidental needle sticks.

## B. THE DOMBROWSKI PATENT

### 1. Claim 18

#### a. Claim Interpretation

1. The Claim describes a method for catheterizing a patient.

2. The method described by the claim involves the insertion of a portion of the shaft of a catheter assembly into a patient. The catheter shaft is described as having proximal and distal ends.

3. The Claim requires that the catheter shaft surround a needle which is intended to serve as the introducer of the catheter.

4. The Claim requires that the needle shall be withdrawn through the catheter shaft once the catheter is in place in the patient's vein.

5. The Claim describes the procedure of capping the distal tip of the needle after withdrawal from the patient's vein. The cap is moved from the hub of the needle to its ultimate position covering the needle tip.

6. The Claim requires friction fitting the catheter over the cap.

7. The Claim describes the need to release the friction fit once the cap has been placed in position at the distal tip of the needle.

#### b. Literal Infringement

Becton Dickinson strenuously argues that it is the requirements of Elements 5, 6 and 7 or some combination thereof that prevent a finding of literal infringement against the accused device. In support of its position, Becton Dickinson relies mainly upon the testimony of its expert, Mr. Fischell. Mr. Fischell testified that the mechanical interference fit by

which the catheter hub and needle guard of the accused device are held together is completely different from the friction fit described by the Dombrowski claim. (Tr. at 911-13). In its briefing, Becton Dickinson contends that Critikon's expert, Mr. Vaillancourt, conceded the differences between the two techniques. (Tr. at 235-38). The Court has closely examined the testimony of both experts and finds that when read in the context of the entire presentation, Mr. Vaillancourt did not concede the differences between the two techniques asserted by Becton Dickinson.

In determining whether the Becton Dickinson accused device infringes the elements of Claim 18 of the Dombrowski Patent, the Court must substantially rely on the evidence presented by each party's expert witness. As described above, Mr. Vaillancourt and Mr. Fischell have divergent views of the intrinsic function of the accused device and how its functioning may fall within the elements of Claim 18. The Court has carefully reviewed the testimony of each expert witness in this regard and the testimony's ability to withstand the challenge of cross-examination. The Court credits Mr. Vaillancourt's views. For example, on page 117 of the Trial Transcript where Mr. Vaillancourt discusses Element 6 of Claim 8:

> Q Now, Element 6 is:
>
> By friction fitting a hub of the catheter over the cap.
>
> Is that done in the Becton Dickinson Saf-T-Cath™ by friction fitting a hub of the catheter over the cap?
>
> A Referring to, perhaps, the best one here is Figure 3A of the Becton Dickinson Service Manual for just a moment, that shows that the green, which is the needle guard, is fixed over the needle, certainly with the flanges there and fixed over the outer flange of the catheter hub. That's the mechanical interference.

Q Is it, in fact, over the cap?

A Excuse me?

Q Is it, in fact — the friction — is it a friction fitting the hub of the catheter over the cap?

A Yes, it is.

Take a look at Figure 3B and you see that the nose of the needle guard is within the hub of the catheter.

Q Now, where is the nose of the needle guard.

A Just move a little bit to the right. That's it right there, the brownish area. That's — the nose is totally within the catheter there.

Q And finally, the last element in this method in Claim 18 is:

Releasing friction fit when the cap is moved to the position capping the distal tip of the needle.

Is that step met?

A That step is met and, I believe, it's clearly shown in, again, in Figure 5B of the Becton Dickinson Service Manual where the green element, which is the needle guard, which is now frictionally released from the catheter hub.

Q Were those all the elements of Claim 18 of the Dombrowski [P]atent?

A Yes, that's the last element.

(Tr. at 117-18).

When Becton Dickinson's counsel challenged Mr. Vaillancourt on cross-examination with regard to the above testimony, the following colloquy occurred:

> Q. Let's go back to your testimony yesterday on Page 117. If you gave the testimony — let me read it to you again.
>
> "Answer: Referring to, perhaps, the best one here is Figure 3A of the Becton Dickinson Service Manual for just a moment, that shows that the green, which is the nose guard, is fixed over the needle certainly with the flanges there and fixed over the outer flange of the catheter hub. That's the mechanical interference."
>
> Mr. Roper asked you this:
>
> "Question: Is it, in fact, over the cap?"
>
> And just referring back to your testimony. You have given some testimony about something being over the hub. And you answered — excuse me, Mr. Roper said:
>
> "Question: Is it, in fact, — the friction — is it a friction fitting the hub of a catheter over the cap?"
>
> And you answered:
>
> "Answer: Yes, it is."
>
> Then you said:
>
> "Take a look at figure 3B and you see that the nose in the needle guard is within the hub of the catheter."
>
> Do you see that?
>
> A Yes, I do.
>
> Q Okay.

Now, you just agreed with me, did you not, that the nose in the needle guard inside the catheter hub does not touch the catheter hub; correct?

A Well, it's physically impossible not to touch the catheter hub because it is -- when it's in there, it's going to lie in one surface of another.

Q You just agreed with me before that there is a clearance between the two. Remember that testimony?

Do you want to change it now?

A The — the difference is you were talking theoretically there is a clearance, but in practicality, that nose will lie on any catheter — on any unit against one surface. And it is — it's just due to differences in tolerances.

Q Have you examined or made a study with microscopic equipment to prove that?

A You know I haven't.

(Tr. at 239-41).

Then, on redirect examination by counsel for Critikon, the following testimony was adduced at page 253 of the Trial Transcript:

Q Now, referring to the Becton Dickinson accused device, is there a frictional force involved in fitting a hub of a catheter over the cap?

A Yes, there is.

Q In what way?

A The method by which the Becton Dickinson device functions, they have four flanges or four fingers, and those four fingers act to mechanically interfere with the flange of the catheter hub. And that interference is a combination of friction and a compression component.

Mr. Roper: Thank you. I have no further questions, your Honor.

The Court: Any recross?

Mr. Mullowney: No, your Honor.

(Tr. at 253).

The Court is persuaded that in much of his testimony regarding the Dombrowski Patent, Mr. Vaillancourt arrived at his opinions by relying on information produced by Becton Dickinson, as well as his own study of the accused device. It is the nature and depth of Mr. Vaillancourt's views that causes the Court to accept them over those proffered by Mr. Fischell. For these reasons, the Court finds that Critikon has established by a preponderance of the evidence that the accused device must be used by the customers of Becton Dickinson in a way that infringes each of the elements of Claim 18.

c. Doctrine of Equivalents

The Court also finds that the accused device infringes Claim 18 under the doctrine of equivalents. Both the accused device and the invention of Claim 18 have a needle guard that protects the needle tip during the process of withdrawing the needle from the patient's vein through the catheter tube.

Additionally, both use the cap described in the Dombrowski Patent to prevent access to the tip of the needle and both are designed to protect health care workers from accidental needle sticks. (Tr. at 120-21).

2. Claim 19

a. Claim Interpretation

The Court interprets Claim 19 to require Elements 1 through 7 of Claim 18. Moreover, the Court interprets Elements 1 through 7 in the same manner it has interpreted these elements in Claim 18. The Court, however, reads Claim 19 to require the following two additional elements:

8. The Claim requires that the cap, which is seated within the catheter as the needle is removed from the catheter, must be retained. However, the claim does not specifically define the manner in which the cap is secured on the tip of the needle.

9. The Claim requires that the release of the cap not occur until the distal tip of the needle is completely covered by the cap and locked in place.

b. Literal Infringement

The Court finds that Claim 19 recites a method for catheterizing patients. Because the procedure that must be utilized with the Becton Dickinson accused device follows each element described in Claim 19, the use of the method by the customers of the accused device literally infringes Claim 19. Becton Dickinson, by its marketing of the accused device, actively induces this infringement and thus contributes to it.

c. Doctrine of Equivalents

The Court finds that the accused device infringes Claim 19 under the doctrine of equivalents. Both have a needle guard that automatically protects the needle tip when the needle is withdrawn from the patient's vein. Both also use the cap described by Dombrowski to prevent access to the tip of the needle by utilizing a mechanical barrier in front of the tip of the needle. (Tr. at 119-121).

d. Willful Infringement

Critikon seeks a determination that the acts of infringement of Becton Dickinson in this matter were willful. In determining whether or not an act of infringement is willful, the Court must consider the totality of the circumstances presented and decide whether the infringer had a reasonable basis for believing it had a right to engage in the course of conduct it undertook. *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992); *American Medical Sys., Inc. v. Medical Eng'g Corp.*, 6 F.3d 1523, 1530 (Fed. Cir. 1993), *cert. denied*, 114 S. Ct. 1647 (1994).

In this case, the Court concludes that Critikon has not shown by clear and convincing evidence that under the totality of the circumstances, Becton Dickinson engaged in acts of willful infringement. Critikon argues that Becton Dickinson's failure to obtain an opinion of counsel with respect to the accused device after having full knowledge of the existing patents in suit demonstrates under the appropriate standard that the infringing acts were willful. In support of this position, Critikon relies upon some internal correspondence produced by Becton Dickinson, which indicates that Becton Dickinson might have been aware that its accused device infringed. (Pl.'s Ex. 33). However, the Court finds that the evidence that Critikon relies upon in support of a finding of willfulness is rebutted by other evidence adduced at trial by Becton Dickinson including some opinions of counsel. (Pl.'s Ex. 478).

Moreover, Becton Dickinson argues strenuously that, despite the ultimate fact that its accused device, i.e., the Saf-T-Cath™ product may infringe the Lemieux and Dombrowski Patents, the device was independently developed and therefore a finding of willfulness is not appropriate.

The Court is persuaded that the development of a safety catheter during the late 1980s and early 1990s was a highly

competitive endeavor, and those engaged in the undertaking were moving quickly to both develop and market a product. Considering these circumstances, the Court understands how Becton Dickinson may have been less cautious than it ordinarily might have been in assessing its positions vis-a-vis a competitor's recently issued patents. Moreover, it is the accuser's obligation to bring forth evidence of willful conduct. In this case, as the Court has stated, although there are signs of Becton Dickinson's imprudence, the Court does not believe that the evidence adduced by Critikon amounts to a finding that Becton Dickinson engaged in acts of willful infringement.

## III.

## INVALIDITY

Becton Dickinson contends that the Dombrowski Patent is invalid on the following grounds: (1) Claims 18 and 19 of the Dombrowski Patent are anticipated by the Lemieux Patent; (2) Claims 18 and 19 are invalid for obviousness; and (3) Claims 18 and 19 are invalid under 35 U.S.C. § 112 because they do not call for the use of a device containing a tether.

### A. ANTICIPATION — SECTION 102

Becton Dickinson has the burden of proving invalidity under 35 U.S.C.§ 102 and by clear and convincing evidence. *Atlas Powder Co.* v. *E. I. Du Pont de Nemours & Co.,* 750 F.2d 1569, 1573 (Fed. Cir. 1984). To establish anticipation, Becton Dickinson must prove that a prior art reference shows each and every element claimed. *Mannesmann Demag Corp.* v. *Engineered Metal Prods. Co.,* 605 F. Supp. 1362, 1367-68 (D. Del. 1985), *aff'd,* 793 F.2d 1279 (Fed. Cir. 1986). Further, anticipation will only be found if "'all elements of a claimed invention arranged as in the claim' can be found in a single prior art reference." *Id.* at 1368

(quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). The Court concludes that Becton Dickinson has failed to carry its burden of proving its contention that the Dombrowski Patent is anticipated by the Lemieux '207 Patent.

Becton Dickinson argues that the Lemieux '207 Patent discloses each element of the Dombrowski Claims 18 and 19 as Critikon construes them. However, at trial Becton Dickinson's expert on this contention, Mr. Fischell, testified as follows:

> Q All right. So the closed corner would be right in front of the needle tip; is that right?
>
> A Yes.
>
> Q Okay. Now, do you understand that it is Critikon's position that this Claim 18 of Dombrowski should be interpreted such that capping is that kind of Dombrowski capping?
>
> A Yes, I do believe that this is what the BD people are of the opinion. I think that is my opinion. It should be, according to the teachings of the drawing.
>
> Q Okay, fine.
>
> Now, Lemieux doesn't have that, does it?
>
> A No. Lemieux does not have exactly that. And if you remember, we say it would infringe Claim 18 if it was construed as Critikon is construing Claim 18 of Dombrowski.
>
> Q That is exactly how we are construing it, isn't it? The capping means, that the closed corner should appear in front of the needle tip?
>
> A I must say that I don't remember those exact words, that is the only way you can — you can construe it precisely that way.

Q In any way, you think that it is the proper way to construe it; isn't that correct? Isn't that what you just testified to?

A Yes, I think that would be a proper way to construe it.

Q So properly construed, the claim would not read on Lemieux. Correct?

A That is my opinion, properly construed, it would not. It does require a force from a tether, which causes the needle point to have a force against the inside of the cap in order to be the Dombrowski design and infringe Claim 18 of Dombrowski.

Q So, in your view, properly construed, that claim is not anticipated by Lemieux?

A Yes. I believe if it were properly construed, to require a tether and to have contact between the needle point, with some force against the inside of the cap, I believe that is the proper interpretation. And in that case, I believe Lemieux would not infringe.

(Tr. at 920-24).

Based on this testimony, Critikon argues that Lemieux '207 Patent cannot anticipate Claims 18 and 19 of the Dombrowski Patent simply because Lemieux does not disclose the type of cap as disclosed by Dombrowski. Based on the record before it, the Court concludes that Critikon's position is the correct one, and thus the Court concludes that Becton Dickinson has failed to establish by clear and convincing evidence that the Lemieux '207 Patent specifically and without deviation discloses each element of Claims 18 and 19 of the Dombrowski Patent.

B. Obviousness — Section 103[1]

Becton Dickinson contends that under 35 U.S.C. § 103, Claims 18 and 19 of the Dombrowski Patent would have been obvious to a person of ordinary skill in the art over the Vaillancourt '267 patent with the additional concept of a friction fitting catheter hub assembly.

Section 103 states:

> A patent may not be obtained . . . if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103 (1988). In order for a court to make a determination of obviousness it must be established:

> [W]hether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and expectation of success must be founded in the prior art, not in the applicant's disclosure.

*In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) (citations omitted).

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[1] Becton Dickinson contended at trial that Claims 8, 21 and 56 of the Lemieux Reissue Patent are invalid under 35 U.S.C. § 103 by combining the teachings of the McDonald '718 patent with the Vanderhoof '811 patent. Becton Dickinson, through the testimony of Mr. Fischell, asserted that the so-called "McHoof" combination would have been obvious to one of ordinary skill in the art. The Court concludes that Becton Dickinson failed to establish by clear and convincing evidence its "McHoof" creation was a combination that a person skilled in the art would have made, in view of the many problems that "McHoof" suffers. (Tr. at 1065-73).

In this case, Becton Dickinson asserts that the evidence demonstrates that the Lemieux '207 Patent, which is prior to art to the Dombrowski Patent, would have led a person of ordinary skill in the art in 1988 to friction fit a hub of a catheter assembly over the needle guard cap of the Vaillancourt '267 Patent and to use the creative device to practice the method called for by Claims 18 and 19 of the Dombrowski Patent.

In response, Critikon argues that the Vaillancourt '267 Patent does not disclose an I.V. catheter nor a device like Dombrowski's which shields the tip of the needle without the performance of an extra manual step by the health care worker. For this reason, Critikon concludes that Becton Dickinson has failed to establish by clear and convincing evidence its claim of invalidity under section 103. At trial, Mr. Vaillancourt was shown Defendant's Exhibits 252 and 331 which were patents issued to Mr. Vaillancourt. The patents represented by the exhibits were testified to by Mr. Vaillancourt as patents that show hypodermic needle guards. When directly questioned regarding the '267 Patent after being show a video of that patent, Mr. Vaillancourt was asked:

> Q And there is disclosure in that Patent (*referring to the '267 patent*) for a little finger that extends to bias the cap as we have just depicted there.
>
> Is that fair?
>
> A No.

(Tr. at 123).

Despite repeated efforts throughout the next several minutes of examination, Mr. Vaillancourt was unwavering in his opinion with regard to what his '267 Patent taught, which was not what Becton Dickinson's counsel sought to prove through Mr. Vaillancourt's testimony. After hearing Mr. Vaillancourt's testimony, the Court is convinced that

the combination proposed by Becton Dickinson has not been shown by clear and convincing evidence to be a combination that one of ordinary skill in the art would have undertaken during the relevant time period. For that reason, the Court concludes that Becton Dickinson has failed to carry its burden under section 103.

C. Enablement — Section 112

Becton Dickinson also contends that Claims 18 and 19 of the Dombrowski Patent are invalid under 35 U.S.C. § 112 because those claims do not specify a tether to hold the Dombrowski cap in place, which Becton Dickinson contends is an essential element of the Dombrowski invention. In essence, Becton Dickinson argues that Claims 18 and 19 are not supported by an enabling disclosure and therefore are invalid under section 112.

Critikon argues that the Dombrowski claims need not be limited to a specific embodiment such as a tether and asserts that one skilled in the art would know that prior art techniques such as those disclosed in the Lemieux '207 Patent could be used in conjunction with practicing the Dombrowski invention.

Section 112 of Title 35 of the United States Code requires that the patent specification contain a description of the invention sufficient to enable one skilled in the art to make and use the claimed invention. 35 U.S.C. § 112 (1988). The standard of specificity is whether one of ordinary skill in the art would understand what is claimed when the claim is read in view of the specification. *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984).

The Dombrowski Patent does disclose a tether to retain its cap on the tip of the needle once the health care worker has completed the insertion of the catheter. It is clear that section 112 permits the enablement requirement to be met by methods that are known in the prior art of which one of

ordinary skill in the art would be aware. Further, the burden of establishing that one of ordinary skill in the art would be unable to utilize the prior art to practice the Dombrowski invention rests with Becton Dickinson. The Court concludes that Becton Dickinson has failed to carry this burden by clear and convincing evidence. As Critikon has argued, the parties stipulated that the Lemieux '207 Patent is prior art to the Dombrowski invention, and it is not unreasonable to conclude that one of ordinary skill in the art would have had this knowledge when construing Claims 18 and 19 of the Dombrowski Patent.

D. Inequitable Conduct

Becton Dickinson contends that the Lemieux '207 Patent which issued on August 28, 1990, and the Lemieux Reissue Patent which issued on October 19, 1993, are unenforceable because the patentee engaged in inequitable conduct before the PTO. Becton Dickinson asserts that during the prosecution of both applications, the attorneys representing the patentee knew of and appreciated the significance of the United States Patent No. 4,834,718 (the "McDonald '718 Patent") and failed to disclose it as prior art.

One inviolable rule of the United States patent process is that applicants and their attorneys must "disclose to the Patent and Trademark Office information they are aware of which is material to the examination of the application." 37 C.F.R. 1.56 (a) (1989). In this regard, applicants for patents and attorneys representing applicants owe the PTO a duty of candor, good faith and honesty. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 n.8 (Fed. Cir. 1987); *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1538 (Fed. Cir. 1984).

A party who alleges inequitable conduct by another based on the failure to disclose material prior art must demonstrate by clear and convincing evidence:

> (1) prior art or information that is material; (2) knowledge chargeable to the applicant of that prior art or information and of its materiality; and (3) failure to the applicant to disclose the art or information resulting from an intent to mislead the PTO.

*FMC Corp.*, 835 F.2d at 1415 (footnote omitted).

For the Court to conclude that inequitable conduct is present, it must first find that certain thresholds of materiality and intent are present. *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1559 (Fed. Cir. 1987).

Information is considered material if "there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56 (a) (1989). However, an applicant need not disclose prior art which is merely cumulative to that already considered by the examiner. *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1107 (Fed. Cir. 1986).

In conducting its analysis the Court must also be convinced that an intent to mislead or deceive the PTO is present. Because direct evidence of an intent to deceive rarely exists, the Court may rely on circumstantial evidence leading to an inference of intent to mislead as the basis for a finding of inequitable conduct. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1562 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 1076 (1990).

Once the Court finds that material information existed that was not disclosed to the PTO and an intent to mislead or deceive was present, the Court must balance the degree of materiality against the degree of culpability. *Halliburton*

*Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991). In balancing, materiality and intent are inversely related. Thus, "the more material the admission, the less culpable the intent required, and vice versa." *Id.* (citing *N.V. Akzo v. E. I. Du Pont de Nemours*, 810 F.2d 1148, 1153 (Fed. Cir. 1987)).

In this case, Becton Dickinson asserts that the McDonald '718 Patent is highly material to the patentability of the Lemieux claims because it is the only prior art that discloses the concept of automatic or nonmanual operation. At trial, Becton Dickinson's expert, Mr. Fischell, testified that none of the prior art considered by the patent examiners during either of the Lemieux prosecutions disclosed a catheter device of the nature disclosed in the McDonald '718 Patent. Mr. Fischell testified that the lack of such a prior art disclosure is highly material in that it is this disclosure in the McDonald '718 Patent that was considered the point of novelty of Lemieux by the examiner. (Tr. at 790).

In further support of its inequitable conduct claim, Becton Dickinson cites the conduct of Britain Yorks, who was responsible for the original Lemieux prosecution through the end of 1989, and Paul Colletti, who took over the prosecution from Mr. Yorks in January of 1990. There is no denial by Critikon that both were aware of the McDonald '718 Patent during the course of their representation. Specifically, Becton Dickinson charges that while Mr. Colletti did not cite the McDonald '718 Patent to the patent examiner during the February 1990 claim amendment process or again in May of 1990, it was at a time when Mr. Colletti clearly understood the materiality of the retaining mechanism to hold the needle guard in place with a catheter hub as described in the McDonald '718 Patent. In this regard, Becton Dickinson cites two instances where Mr. Colletti revealed the McDonald '718 Patent as prior art to the PTO

when dealing with issues involving intravenous catheters. (Colletti Dep. at 335).

Critikon responds to the allegations of inequitable conduct by arguing that the failure to disclose the McDonald '718 Patent to the PTO during the Lemieux prosecutions was not done with an intent to deceive or mislead the PTO and that the McDonald '718 Patent was not material to the PTO's consideration of the proposed patent. In arguing that the McDonald '718 Patent was immaterial, Critikon contends that the disclosures of the '718 Patent teach a manually operated needle guard of a large size that covers the entire needle. Critikon contends that such a device is objectively very different from the subject matter that was claimed by the Lemieux patents. Further, Critikon argues that the McDonald '718 Patent does not disclose a safety catheter having a needle guard that moves into position absent an extra step by the health care worker. Critikon supports its position by citing the testimony of Becton Dickinson's expert, Mr. Fischell. (Tr. at 950-53). In sum, Critikon asserts that because the McDonald '718 Patent discloses a device which is substantially different from the device disclosed by the Lemieux Patents that the McDonald '718 Patent was not material prior art to the Lemieux application and in fact affirmatively teaches away from the Lemieux invention. (Tr. at 748-55, 945-55).

The Court has reviewed the testimony and exhibits presented by both parties regarding the alleged inequitable conduct. On the record before it, the Court finds that Critikon was aware and had knowledge of the McDonald '718 Patent during the Lemieux prosecutions. However, the Court finds that even assuming the McDonald '718 Patent was material to the patent examiner's consideration of the Lemieux applications, the failure of Critikon to disclose it was not intentional nor designed to mislead the patent examiner. The Court is persuaded by the testimony of both

expert witnesses that the McDonald '718 Patent teaches a device that is substantially different than that contemplated by the Lemieux patents. Further, the Court has weighed the testimony of both Mr. Yorks and Mr. Colletti and determined that their explanations for not disclosing the McDonald '718 Patent are credible under the totality of the circumstances. For these reasons, the Court concludes that Becton Dickinson has failed to establish by clear and convincing evidence that the Lemieux Patent should be declared unenforceable on the basis of inequitable conduct by Critikon.[2]

## IV.

## REMEDIES

### A. DAMAGES

Critikon seeks to recover its alleged lost profits. Becton Dickinson argues that as a matter of law a patent holder must demonstrate it has the capability to meet the market demand for the patented product. *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978).

Becton Dickinson contends that because Critikon does not practice the patents-in-suit, it cannot legally sustain a claim for lost profits in view of the market demand requirement of *Panduit. See Trilogy Communications, Inc., v. Comm Scope Co.*, 754 F. Supp. 468 (W.D.N.C. 1990).

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[2]The allegations of Becton Dickinson of inequitable conduct as evidenced by the alleged failure of Critikon to disclose the Luther United States Patent No. 4,832,696 has not been addressed by the Court because Becton Dickinson failed to adduce any credible evidence at trial in support of this claim.

Critikon counters that the Federal Circuit does not require that a patent owner practice the patent-in-suit to recover lost profit damages.

The Court finds substantial merit in the reasoning of the *Trilogy Communications* decision. It certainly seems illogical to award lost profits for a patent that has not been commercialized in the market place. However, to bar a lost profits recovery by Critikon under the legal theory espoused by Becton Dickinson, the Court would seek additional limited briefing by the parties on the effect and scope of the market demand criterion under *Panduit*.

On the other hand, the Court has reviewed each party's submission with regard to what would constitute a reasonable royalty under the circumstances of this case and is prepared to set a reasonable royalty if Becton Dickinson prevails on its lost profit theory.

Therefore, the Court will request Critikon to advise the Court by a date certain whether it desires to pursue its lost profits recovery. If Critikon chooses to pursue such damages, the Court will set a briefing schedule, however, if Critikon abandons its lost profits claim, the Court will enter a decision on a reasonable royalty.

B. Permanent Injunction

The Court concludes that for the reasons already discussed in its July 16, 1993 Opinion that Critikon is entitled to injunctive relief against Becton Dickinson's infringing activities. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, Civ. A. No. 93-108-JJF, at *5 (D. Del. July 16, 1993). Critikon shall submit a Proposed Form of Permanent Injunction Order no later than July 25, 1994. Becton Dickinson may submit its views on the Proposed Order no later than August 1, 1994. If the parties can agree on the Form of Order, they shall submit it no later than July 25, 1994.

95-1322, 95-1363

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

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CRITIKON, INC.,
*Plaintiff-Cross Appellant,*

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,
*Defendant-Appellant.*

# ORDER

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

**ORDER**

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLANT, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on October 1, 1997.

FOR THE COURT,
JAN HORBALY, CLERK

Dated: September 24, 1997

By: [signature]
Alex Van Veen
Staff Law Clerk

cc: EDWARD F. MULLOWNEY
HARRY J. ROPER

CRITIKON, INC v. BECTON DICKINSON,
95-1322, -1363 (DCT - 93-108)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent.
It is a public record.

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June 11, 1991

Richard J. Rodrick, Esq.
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One Becton Drive
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Re: U.S. Patent No. 4,978,344 (Dombrowski *et al.*)
Your Ref.: P-1741
Our Docket: 102-53

Dear Rich:

## SUMMARY

We have conducted a study of U.S. Patent No. 4,978,344 for the purpose of determining whether it includes claims which cover a proposed catheter introducer assembly as described in Appendix A. Based upon our study, we are of the opinion that the '344 patent includes no valid claims which would cover the proposed assembly. We are also of the opinion that a number of the claims of this patent would be held invalid if tested unless the patentee were able to demonstrate a date of invention considerably earlier than the effective filing date.

## DISCUSSION

We have reviewed the '344 patent, its file history, and the references cited against this application in the course of our study. Additional prior art not cited against that patent was also reviewed.

### I. File History

A. Filing of Application: The application which matured into U.S. Patent No. 4,978,344 is a continuation-in-part of application serial No. 231,053 filed August 11, 1988, now abandoned. The parent application included Figs. 1-7 of the case which matured into the '344 patent. Figs. 8-10 were added to the application filed December 27, 1988, which issued on December 18, 1990.

B. Initial Action (9/21/89): Following a restriction requirement, the elected claims were rejected as unpatentable over U.S. Patent No. 4,846,809 (Sims) either alone or in view of two secondary references. A number of formal objections were also made.

C. Response to Initial Action (10/18/89): In addition to attending to the various formal objections raised by the Examiner, the applicant's attorney amended the claims and provided arguments for the purpose of distinguishing the amended claims from the applied references. In doing so, he made a number of erroneous statements with respect to the Sims patent which apparently were not detected by the Examiner, as evidenced by the subsequent allowance of claim 27 and 29 as amended (claims 18-19 of the issued patent). Specifically, applicant's attorney stated:

> 1) "the sleeve . . . has sufficient elasticity to force the protective cap outwardly but not over the tip of the needle. The cap must then be manually forced over the tip if the needle is to cover the tip of the needle."

2) "there is no frictional fit between the catheter and the cap (94) such that the catheter moves the cap over the needle and over the distal tip of the needle."

The Sims patent disclosure is quite clear in its teaching that the elastic sleeve (92) of the Sims device (shown below)

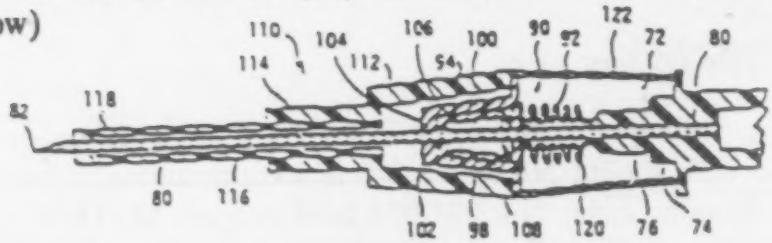


FIG. 8

pushes the needle cap (94,98) over the needle tip as the needle (80) is withdrawn from the catheter tube (118). (Col.11, lines 25-39; col. 9, lines 9-16). It is only when the sleeve is non-elastic that one must manually push the cap (94,98) over the needle tip (col. 8, lines 58-64).

The patent also states that the "intravenous catheter arrangement 110 comprises a conically shaped body 112 which is disposed about and retentively held on the protective cap 94, in the manner as best illustrated in Fig. 8." (emphasis supplied). Fig 8 is actually poorly drawn, and shows a gap between the catheter adapter 112 and the cap 94. Fig. 10 better illustrates the manner in which the catheter adapter 112 is retentively held on the cap 94, as clearly described in the specification.

Applicant's attorney attempted to distinguish claim 27 by stating that "there is no step of frictionally fitting a cap into a catheter nor is the releasing step [of the friction fit] disclosed in the Sims patent." This step was added by amendment to the claim. We believe the Sims patent discloses both of these steps, and renders claim 27 invalid.

D. Final Action (11/3/89): Apparatus claims 1 and 4, and method claim 31 continued to be rejected as anticipated

by Sims. Claim 5, 6, 27, 29 and 30 were indicated to be allowable. U.S. Patent Nos. 4,762,516 and 4,832,696, both to Luther et al., were cited for the first time, but not applied.

E. Response After Final (1/5/90): Claims 1 (1) and 31 (21) were amended to define over Sims, while claim 27 (18)* was amended in response to a formal objection. The same erroneous statements made in the previous response were repeated by applicant's attorney with respect to the Sims patent.

F. Notice of Allowability/Reasons for Allowance

A Notice of Allowability was issued on January 11, 1990. The Examiner stated:

> "the patent to Sims shows structure very similar to Applicant's device's structure, but differs in that the needle cap of the Sims device is not held in the catheter by any means, but is only biased to the hub, and is therefor not operatively secured' thereto as is the case with Applicants' device's needle cap.

The Examiner's statement ignores the description provided by Sims that the catheter hub 112 is "disposed about and retentively held on the protective cap 94. Sims does not use the term "biased." He used "retentively held on."

## II. Validity

Claims 1-17 and 20-22 are clearly avoided by the proposed device, as discussed below. Claims 18 and 19 of the '344 patent are certainly not literally infringed by the proposed device. Analysis of the claims with respect to the prior art is warranted, however, to determine not only whether these claims are valid, but whether they are relatively broad or narrow in scope.

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*Corresponding claims of issued patent indicated in parentheses.

**A. Claim 1**

It is our opinion that claim 1 would be found invalid under 35 U.S.C. 102 (e)/103 over Sims in view of U.S. Patent No. 4,952,207 (Lemieux) if litigated. Sims discloses every element except locking means for locking the cap over the needle tip. Lemieux discloses such locking means.

**B. Claims 18-19**

Claim 18, if construed broadly enough to cover the proposed device, is anticipated under 35 U.S.C. §102 (e) by U.S. Patent Nos. 4,762,516 (Luther et al.), 4,846,809 (Sims), and 4,952,207 (Lemieux). A claim chart is provided in Appendix B which relates each claimed step with the disclosure of such a step by each reference.

We are cognizant of the fact that both Luther et al. and Sims were cited and applied, respectively, by the Patent and Trademark Office during the prosecution of the Dombrowski et al. patent. The presumption of validity of the claims of the patent accordingly is not weakened with respect to these references as it is with Lemieux which was not cited. EWP Corp. v. Reliance Universal Inc., 755 F.2d 898, 905 (Fed. Cir. 1985). As discussed above, we do believe the Sims patent was misdescribed by the attorney who prosecuted the case and misinterpreted by the Examiner.

Luther et al. may not have been applied by the Examiner as the needle guard disclosed therein is substantially outside the catheter adapter. The proposed device shares this distinction. Luther et al. does not specifically describe the manner in which the catheter assembly is mounted to the needle guard and needle shaft. (Col.2, lines 25-27). The needle guard includes a conical projection which extends within the catheter adapter. We are aware of a number of catheter introducer assemblies having such projections which have been commercially available for many years. The catheter adapter is virtually always frictionally coupled

to such projections. (See, e.g. U.S. Patent No. 4,417,886 (Frankhouser et al.). We believe we can safely assume the Luther et al. catheter adapter is frictionally coupled to the projection extending from the needle guard. If not, it would certainly be obvious to provide such a coupling. Claim 18 accordingly reads on a procedure which was disclosed by Luther et al. in an application filed seventeen months before the effective filing date of the '344 patent, and is invalid (if construed to cover the proposed device) unless the patentee can establish a prior date of invention.

Claim 19 further defines the "moving" step of claim 18. It requires "retaining the cap (34) seated within the catheter (14) as the needle (26) is removed from the catheter (14)" and "releasing the cap (34) from the catheter (14) as the distal tip (32) of the needle (28) completely enters the cap (34) and is locked therein."

This claim is fully anticipated by Lemieux under 35 U.S.C. §102(e). Sims discloses everything with the exception of the needle tip within a cap. Such locking is obvious in view of Lemieux. Finally, Luther et al. anticipates this claim if construed broadly enough to cover the proposed device.

While Sims and Lemieux both disclose needle guards positioned entirely within the catheter adapter, the Luther et al. construction is more similar to the one embodiment of the proposed device where only a small projection extending from the needle guard is positioned within the catheter hub. If claims 18 and 19 are interpreted broadly to include comparable devices where any portion of a guard extends within a catheter adapter, they will read on Luther et al. If read more narrowly, they will fail to read on the proposed device.

**Potential Infringement**

**A. Claims 1-17**

Claims 1-17 are clearly avoided by the proposed device as they all require "tether means" for connecting "said cap means (34) to said first hub means (16)." The proposed device includes no such means. The needle shaft cannot be considered equivalent to "tether means" as it is not extendible in the manner as claimed.

**B. Claims 18-20**

Claims 18-20 are method claims. All of these claims require friction fitting the hub of a catheter over a cap (i.e. guard). The proposed device does not fit the catheter hub over a cap. If read broadly enough to cover the positioning of a small projection of a cap into a needle hub, the claim would read on Luther et al. as discussed above. We believe the patentee would be estopped from reading the claim this broadly in view of amendments made by the patentee to add the fitting of a catheter hub over a cap, and arguments directed to such an arrangement.

Claim 19 includes no additional limitations to distinguish it from Luther et al. The broad interpretation of claim 19 discussed above would accordingly result in the invalidity of this claim in view of Luther et al.

Claim 20 requires the use of a tether, and is clearly avoided by the proposed device from the same reason as claim 1.

**C. Claims 21-22**

Claims 21-22 are both directed to the insertion of a needle through a sealed end of a catheter port. This procedure is shown in Figs. 8-10 of the '344 patent. The proposed device is at least primarily used for insertion within a blood vessel. Such use would not infringe these claims.

## CONCLUSION

It is our opinion that the claims of the '344 patent are avoided by the proposed device. The proposed device and its primary method of use do not literally read on the claims. The prosecution history and prior art preclude the claims from being read so broadly as to cover the proposed devices.

We are also of the opinion that a number of the broader claims of the patent would be held invalid if litigated. As the art which renders these claims invalid was published less than one year prior to the effective filing date of the '344 patent, it would be possible for the patentee to attempt to prove an earlier date of invention, thereby antedating this art. We note, however, that the patentee made no attempt to antedate the February 24, 1988 filing date of the Sims patent, which leads us to believe that at least Sims and Luther et al. would be available as prior art references. Lemieux was filed only one month before the parent application of the '344 patent. We would expect Dombrowski et al. would be able to swear behind Lemieux to overcome a §102(e) rejection: 35 U.S.C. §§ (f) and 102(g) would still be possibly available in an inter parties proceeding if Lemieux were applied against the '344 patent. Since we do not have access to their files, we can only conjecture as to which party, Lemieux or Dombrowski et al., would be able to prove first inventorship. The possibility that Lemieux may not be available as a reference does not affect our opinion.

Please feel free to contact us should you have any questions concerning this matter.

Yours very truly,

/s/

A. THOMAS KAMMER

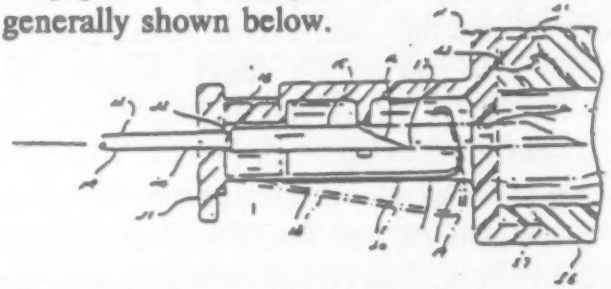
ATK/lld

# APPENDIX A

## The Proposed Assembly

The proposed assembly includes a needle hub having a generally tubular body. A front axial chamber is defined by one end of the body, and a rear axial chamber is defined by the opposite end thereof. A needle support is integrally formed with the body intermediate the two chambers therein. A needle is secured to the support. The needle includes a rear end portion extending into the rear chamber and a front end portion extending through the front chamber. The front end portion of the needle includes a bevelled tip positioned outside the front chamber. A longitudinal slot extends through a portion of the body which defines the front chamber.

A needle tip guard is slidably mounted to the shaft of the needle as generally shown below.



The guard includes a generally tubular body which has an enlarged, generally cylindrical catheter retainer formed at one end thereof. The retainer is adapted for snugly receiving the threaded end of a catheter adapter of an over-the-needle catheter. The tubular body of the guard is partially insertable within the front chamber of the needle hub. It includes a radially extending projection which extends within the longitudinal slot in the needle hub. The enlarged retainer engages the front end of the needle hub when the guard is inserted within the hub, and the bevelled end of the needle projects beyond the distal end of the catheter at this time. The guard and catheter are prevented from sliding down the

needle shaft unless force is applied thereto. This is due to frictional engagement between the needle shaft and the guard and catheter, and between the guard and the hub. No detent mechanism is employed.

The diameter of the needle is substantially constant from its rear end to an area between the needle hub and the bevelled tip of the needle. It increases in a transition zone, and is again substantially constant between the transition zone and the bevelled end. The guard includes a passage having a diameter substantially equal to the relatively small diameter of the needle proximal to the transition zone. The guard accordingly cannot be moved off the end of the needle as it will engage the transition zone before such removal can occur. The distal end of the guard extends over the bevelled tip of the needle when the guard engages the transition zone.

A metal stop member is mounted to the guard for preventing the guard from being moved towards the needle hub once it has been moved to a position wherein it engages the transition zone of the needle. The stop member includes a generally L-shaped body made from spring steel or the like. The L-shaped body includes a radially inwardly extending portion which bears against the needle shaft until it is moved beyond the bevelled tip. It then snaps over the needle tip. Any attempt to slide the guard towards the needle hub will result in the engagement of the needle tip by the stop member.

One embodiment of the proposed assembly includes and axial protrusion extending from the distal surface of the retainer portion of the guard. The catheter adapter is positioned over this protrusion until detached from the retainer.

| U.S. PATENT NO. 4,978,344 | LUTHER, ET AL. | SIMS | LEMIEUX |
|---|---|---|---|
| 18. A method of catheterizing a patient, said method including the steps of: | General disclosure | General disclosure | General disclosure |
| inserting at least a portion of a shaft (40) of catheter assembly (10) defining proximal and distal ends thereof into a patient's blood vessel, | Fig. 3 | Col. 11, lines 13-20 | Col. 4, lines 5-8 |
| the catheter shaft being disposed over a needle, and | Fig. 3 (catheter 31 over needle 22) | Figs. 8,10 | Figs. 1-3 |
| removing the needle (28) from the catheter shaft (40) while | Fig 3A | Col. 11, lines 30-32 | Col. 4, lines 8-10 |
| simultaneously moving a cap (34) from a hub (16) of the needle (28) which is a distal relative to the hub (16) by | Fig. 4: Cap 23 moves from needle hub 14 as needle 22 is removed from a catheter shaft to a position capping the needle tip | Col. 11, lines 32-39 | Col 4, lines 10-25 |
| friction fitting a hub (44) of the catheter (14) over the cap (34) and | Figs 3, 3A and 4 show the catheter hub 30 friction fitted over a portion 26 of the cap | Col. 10, lines 55-57 describe the catheter hub 112 as being disposed about and "retentively held on the cap 94" | Fig. 3 |
| releasing friction fit when the cap (34) is moved to the position capping the distal tip (32) of the needle (28) | Fig. 5 shows the housing 11, which includes the needle and cap, as released from the catheter hub 30. | Col. 12, lines 2-3 | Col. 4, lines 17-25 |